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EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 06/17/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/742,123

Applicant(s)

HARAYAMA ET AL.

Examiner

Arun Chakrabarti

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *Detailed Action*.

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DETAILED ACTION

Specification

1. Claims 1, 2, 4, and 5 have been amended and new claims 6-10 have been added. Claim 3 has been cancelled without prejudice towards further prosecution.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 1-2, and 4-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Stemmer (U.S. Patent 6,180,406 B1) (January 30, 2001).

Stemmer teaches a method for making libraries of hybrid polynucleotide molecules comprising the steps of:

(I) selecting a first single-stranded polynucleotide which corresponds to a coding strand of a first family gene (Example 14, Column 86, line 39 to Column 87, line 7 and Claim 1);

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(ii) selecting a second single-stranded polynucleotide which corresponds to a non-coding strand of a second family gene (Example 14, Column 86, line 39 to Column 87, line 7 and Claim 1);

(iii) fragmenting the two single-stranded polynucleotide molecules to form polynucleotide fragments (Column 23, lines 24-67 and Example 7).

(iii) hybridizing the polynucleotide fragments to form heteroduplex molecules (Column 24, lines 34-51),

(iv) conducting nucleotide elongation on the heteroduplex molecules, wherein the second single-stranded polynucleotide molecules are used as starting materials (Column 24, lines 52-56),

Stemmer teaches a method wherein the first family gene is different from the second family gene and wherein the first single-stranded polynucleotide comprises at least one homologous sequence and at least one sequence which is heterologous to the second single-stranded polynucleotide (Column 86, lines 39-60).

Stemmer teaches a method wherein mutations are introduced into hybrid polynucleotide molecules (Column 24, lines 1-21 and Example 14, Cassette mutagenesis Section, Column 87, line 3 to column 88, line 3).

Stemmer teaches a method for making libraries of hybrid polynucleotide molecules, which comprises:

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(I) preparing two single-stranded polynucleotide molecules comprising sequences which are complementary to each other (Example 14, Column 86, line 39 to Column 87, line 7 and Claim 1);

(ii) fragmenting the two single-stranded polynucleotide molecules (Column 23, lines 25-30 and Example 14, Column 87, lines 8-12).

(iii) incubating the fragmented molecules under conditions such that hybridization of fragmented polynucleotide molecules occurs and de novo polynucleotide synthesis on the hybridized molecules occurs (Column 24, lines 34-56 and Example 14, Column 87, lines 13-17 and Claim 1),

(iv) denaturing the resultant elongated double-stranded polynucleotide molecules into single-stranded polynucleotide molecules (Column 24, lines 27-34),

(V) incubating the resultant single-stranded polynucleotide molecules under conditions such that hybridization of fragmented polynucleotide molecules occurs and de novo polynucleotide synthesis on the hybridized molecules occurs (Column 24, lines 34-56 and Example 14, Column 87, lines 13-17 and Claim 1 and Claim 11c), and

(Vi) repeating at least two further cycles of steps (iv) and (v) (Column 25, lines 1-18 and Claims 12 and 13).

Stemmer teaches a method, wherein at least one or both of the two single-stranded polynucleotide molecules is fragmented randomly (Column 23, lines 24-67 and Example 7).

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Stemmer teaches a method, wherein mutations are introduced into at least one or both of the first and second single-stranded polynucleotides prior to the production of the heteroduplex molecules (Column 24, lines 1-21 and Example 14, Cassette mutagenesis Section, Column 87, line 3 to column 88, line 3).

Stemmer teaches a method, wherein the homologous sequence is at least 15 bases (Column 23, lines 28-30).

Response to Amendment

4. In response to amendment, all 112 (second paragraph) rejections are hereby withdrawn. However, 102 (e) rejection is properly maintained.

Response to Arguments

5. Applicant's arguments filed on May 20, 2002 have been fully considered but they are not persuasive.

Applicant argues that at no place in the referred text of Stemmer is single-stranded DNA fragmented, rather all fragments are made synthetically. This argument is not persuasive. Applicant argues that Stemmer reference does not teach the fragmentation of single-stranded DNA of the claimed invention. Applicant argues that the word "fragmentation of single-stranded DNA" was not found in Stemmer reference and only the word "fragmentation of double-stranded DNA" is found. Applicant argues that because Stemmer has a preferred embodiment of "fragmentation of double-stranded DNA", Stemmer is limited to the preferred embodiment. This

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argument is not persuasive. As MPEP 2123 states "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 169 USPQ 423 (CCPA 1971)." MPEP 2123 also states "A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 10 USPQ2d 1843 (Fed. Cir. 1989)." It is clear that simply because Stemmer has a preferred embodiment, this embodiment does not prevent the reference from suggesting broader embodiments in the disclosure and that this does not constitute a teaching away. Although Stemmer reference uses fragmentation of double-stranded DNA in certain experiments to generate libraries of hybrid polynucleotides the property of fragmenting the single stranded polynucleotides is inherently present in these chemically, biologically and structurally identical molecules. For example, Stemmer teaches, "Any added double or single-stranded fragments are randomly digested into fragments of from about 5 bp to 5 kb or more (Column 23, lines 25-27)". Moreover, MPEP 2111 states, "Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification". Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)". In this case, Stemmer reference

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clearly teaches the fragmentation of single-stranded DNA as mentioned in the current 102 (e) rejection as mentioned above

Applicant also argues that there is absolutely no disclosure in Teodorescu et al reference of use of a bacteriophage which contains nucleic acids labeled with dye or fluorescent substance. This argument is not persuasive. Teodorescu et al reference clearly teaches the use of a bacteriophage which contains nucleic acids labeled with dye or fluorescent substance (Page 9, lines 19-25).

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun Chakrabarti,

Patent Examiner,

June 5, 2002


W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600